

**Claims**

1. A method for regulating a milking process, said method comprising the steps of

- 5           i)     identifying at least one volume of milk,
- ii)    assessing particles in the identified volume by either
- a)   counting of substantially individual somatic cells in the volume of
- 10               milk, or
- b)   assessing at least one property of at least one biological particle
- in the volume of milk,
- iii)   obtaining at least one result of the assessment of particles in the
- 15               identified volume of milk,
- iv)    providing at least one predetermined milk quality parameter,
- v)     correlating the at least one result obtained in step iii) with the
- 20               predetermined milk quality parameter provided in step iv),
- vi)    transferring any one or both of
- c)   the at least one result obtained in iii), and
- 25               d)   the correlation obtained in v)
- to regulating means capable of regulating the milking process of at
- least a portion of the milk being milked, and
- 30           vii)   regulating the milking process based on any one or both of c) the at
- least one result obtained in iii), and d) the correlation obtained in v).

35   2. A method according to claim 1, said method further comprising assessing one or more chemical or physical property of the milk, said assessment preferably

being made substantially simultaneously with the assessment of the particles in the identified volume of milk.

- 5 3. A method according to claim 1, wherein the result of the counting of individual somatic cells is correlated to a value substantially representing the number of somatic cells per volume of milk, by the use of one or more calculated and/or predetermined parameter(s).
- 10 4. A method according to any of claims 1 to 3, wherein the number of individual somatic cells counted is 2 or more, preferably 4 or more, more preferably 10 or more, more preferably 20 or more, more preferably 50 or more, more preferably 100 or more, more preferably 200 or more, more preferably 400 or more.
- 15 5. A method according to any of the preceding claims, wherein the estimated and/or calculated relative error of precision in the counting of the number of individual somatic cells is at the most 30%, preferably at the most 20%, more preferably at the most 15%, more preferably at the most 10%, more preferably at the most 5%, more preferably at the most 2%.
- 20 6. A method according to any of the preceding claims, wherein the estimated and/or calculated relative error of accuracy in the counting of the number of individual somatic cells is at the most 30%, preferably at the most 20%, more preferably at the most 15%, more preferably at the most 10%, more preferably at the most 5%, more preferably at the most 2%.
- 25 7. A method according to claim 1, wherein the assessment of particles is the counting of biological particles present in the milk, the biological particles having diameter of more than 0.1 mm, preferably the biological particles having diameter of more than 0.5 mm, more preferably the biological particles having diameter of more than 1 mm, more preferably the biological particles having diameter of more than 2 mm, more preferably the biological particles having diameter of more than 5 mm.
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8. A method according to claim 1 or 7, wherein the biological particles are one or several of: particles containing protein, particles containing somatic cells, particles containing body tissue.
- 5 9. A method according to claim 1, wherein the assessment of particles is the counting of blood particles.
- 10 10. A method according to claim 2, wherein the assessment of one or more chemical properties is the estimation of the concentration and/or the level of one or more of: fat, protein, lactose, citric acid, urea, haemoglobin, ketones, carbon dioxide, oxygen, pH, potassium, calcium, sodium.
- 15 11. A method according to claim 2, wherein the assessment of one or more physical properties is the measurement of one or more of: temperature, conductivity, light scatter.
- 20 12. A method according to any of claims 1 to 7, wherein the counting of the number of individual somatic cells and/or the correlation of the counting to a value substantially representing the number of somatic cells per volume of milk is done for one or more individual quarter(s).
- 25 13. A method according to any of claims 1 and 7 to 9, wherein the assessment of one or more particles is done for one or more individual quarter(s).
- 30 14. A method according to any of claims 1 or 10, wherein the assessment of one or more chemical properties is done for one or more individual quarter(s).
15. A method according to any of claims 1 or 11, wherein the assessment of one or more physical property is done for one or more individual quarter(s).
16. A method according to any of the preceding claims, wherein the regulation of the handling of the milk is done individually for milk from one or more quarter(s).

17. A method according to any of the preceding claims, wherein the assessment of particles in the milk, and/or the assessment of one or more chemical or physical property of the milk is done substantially before and/or after the identification of the individual animal being milked, preferably where the identification is done by identification means reading one or more data carried by the individual animal.
18. A method according to any of the preceding claims, wherein the determination of whether the animal is to be milked is determined by determination means, the determination means taking into account the identification of the animal and one or more information concerning the time of previous milking and/or one or more information concerning the health of the animal.
19. A method according to any of the preceding claims, wherein the regulation of the handling of the milk is directing the milk to one or more storage means and/or outlets.
20. A method according to any of the preceding claims, wherein the regulation of the handling of the milk is correct in relation to a set of predetermined parameters, in at least 85% of the milking, preferably in at least 90% of the milking, more preferably in at least 95% of the milking, more preferably in at least 98% of the milking.
21. A method according to any of the preceding claims, wherein at least one of the result of the assessment of the volume of milk is/are transferred to a storage means, preferably where the result is/are identified by identification of the animal, the data of the storage means being available to computing means.
22. A method according to any of the preceding claims, wherein the milking apparatus is a automatic milking system.
23. A method according to any of the preceding claims, wherein the assessment of particles is performed by means of automated microscopy methods.

- 5 24. A method according to any of the preceding claims, wherein the assessment of particles is performed by automated microscopy performed by creating a spatial image representation of electromagnetic irradiation from an exposing domain containing a sample of the milk and performing a quantitated detection of the image.
- 10 25. A method according to any of the preceding claims, wherein the volume of the liquid sample from which electromagnetic radiation is irradiated is detected is in the range between  $0.01 \mu\text{l}$  and  $20 \mu\text{l}$ .
- 15 26. A method according to claim 25, wherein the volume of the liquid sample from which electromagnetic radiation is irradiated is detected is in the range between  $0.04 \mu\text{l}$  and  $4 \mu\text{l}$ .
- 20 27. A method according to any of the preceding claims, wherein the signal which is detected for the assessment of particle is a signal which is substantially caused by attenuation of electromagnetic signal, and/or by emission of electromagnetic irradiation by photoluminescence, the attenuation and/or the photoluminescence being associated to one or more molecules which is/are a part of the particle, preferably where the particles are somatic cells and where the molecules are DNA and/or proteins.
- 25 28. A method according to any of the preceding claims, wherein the signal which is detected for the assessment of particles substantially originates from one or several types of molecules of types which bind to, are retained within, or interact with, the particles, such molecules being added to the sample before or during exposure of electromagnetic signals, the molecules being molecules giving rise to one or several of the following phenomena: attenuation of electromagnetic radiation, photoluminescence when illuminated with electromagnetic radiation,
- 30 scatter of electromagnetic radiation, raman scatter.
29. A method according to claim 28, wherein an effective amount of one or more nucleic acid dyes and/or one or more potentiometric membrane dyes is added.

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30. A method according to claim 29, wherein a nucleic acid dye or nucleic acid dyes is/are added in an amount of 0.3-30  $\mu\text{g}$  per ml of the sample.
- 5 31. A method according to any of claims 29 to 30, wherein there is/are added one or more nucleic acid dyes selected from the group consisting of: phenanthridines (e.g. ethidium bromide CAS#: 1239-45-8, propidium iodide CAS#: 25535-16-4), acridine dyes (e.g. acridine orange CAS#: 65-61-2/CAS-10127-02-3), cyanine dyes (e.g. TOTO<sup>TM</sup>-1 iodide CAS#: 143 413-84-7 -Molecular Probes, YO-PRO<sup>TM</sup>-1 iodide CAS#: 152 068-09-2 -Molecular Probes), indoles and imidazoles (e.g. Hoechst 33258 CAS#: 023 491-45-4, Hoechst 33342 CAS#: 023 491-52-3, DAPI CAS#: 28718-90-3, DAPI (4',6-(diimidazolin-2-yl)-2-phenylindole)).
- 10 32. A method according to any of claims 28 to 30, wherein the nucleic acid dye added is propidium iodide CAS#: 25535-16-4.
- 15 33. A method according to any of claims 28 to 33, wherein any chemical added has the effect of aiding in the binding of one or more dyes to a particle, preferably such chemical being t-Octylphenoxypolyethoxyethanol (Triton X-100).
- 20 34. A method according to any of claims 28 to 32, wherein any chemical has been added to the sample on a substantially solid, and/or substantially non-aqueous, and/or substantially freeze dried form.
- 25 35. A method according to claim 34, wherein any chemical added has the effect of increasing the rate of dissolution or solubilisation of any chemical on substantially solid, and/or substantially non-aqueous, and/or substantially freeze dried form, preferably such chemical being one or more types of organic or inorganic salts.
- 30 36. A method according to any of the preceding claims, wherein the assessment of any chemical property is based on spectrophotometric measurement, the spectrophotometric measurement being, e.g., one or several of; mid-infrared attenuation, near-infrared attenuation, visible attenuation, ultra-violet attenuation, photoluminescence, raman scatter, nuclear magnetic resonance.

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37. A method according to any of the preceding claims, wherein the assessment of any chemical property is based on potentiometric measurement, preferably by the use of an ion selective electrode.

38. A method according to any of the preceding claims, wherein the volume of milk being assessed is a sample of milk which is undiluted, except for the addition of the reagents used in the assessment, preferably the reagents being on a substantially solid, and/or substantially non-aqueous, and/or substantially freeze dried form.

39. A method according to any of the preceding claims, wherein at least a part of the volume of milk being assessed is acquired and/or identified substantially at the beginning of milking, preferably before 100 ml of milk have been milked, more preferably before 20 ml of milk have been milked, more preferably before 5 ml of milk have been milked.

40. A method according to any to any of the claims 1 to 39, wherein the volume of milk being assessed is acquired and/or identified substantially during the entire milking, preferably where the composition of the milk is a substantial representation of the entire milk being milked.

41. A method according to any to any of the claims 1 to 39, wherein the volume of milk being assessed is a collected at different times during milking, preferably where the result of one or more assessment can be correlated to the property of the entire milk being milked.

42. A method according to any of the preceding claims, wherein at least one of the assessment of particles, or chemical or physical property of milk is performed in a substantially disposable device, preferably where the device is discarded or disposed of after the assessment of a predetermined number of volumes of milk.

43. A method according to any of the preceding claims, wherein at least one of the assessment of particles, or chemical or physical property of milk is performed in

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a substantially disposable device, preferably where the device is discarded or disposed of in the event it becomes at least partially blocked.

5 44. A method according to any of the preceding claims, wherein at least one of the assessment of particles, or chemical or physical property of milk is performed in a substantially disposable device, preferably where the device is discarded or disposed of in the event it has become substantially empty of any chemical or reagent used for the assessment.

10 45. A method according to any of the preceding claims, wherein at least one of the assessment of particles, or chemical or physical property of milk is performed in a domain where at least one physical dimension of the domain substantially partly determines the volume of the domain, and where the at least one physical dimension is substantially different during at least a part of any period when a sample is introduced to the domain and at least a part of any period when a measurement or detection is performed, preferably where the effect is such that the volume of the domain is substantially larger during at least a part of any period when a sample is introduced to the domain than in at least a part of any period when a measurement or detection is performed.

15 46. A method according to claim 45, wherein the volume during at least a part of any period when a sample is introduced to the domain is at least 10% larger than the volume during at least a part of any period when a measurement or detection is performed, preferably where the volume is 25% larger, more preferably where the volume is 50% larger, more preferably where the volume is 100% larger, more preferably where the volume is 200% larger, more preferably where the volume is 400% larger.

20 47. A method according to any of the preceding claims, wherein at least one of the assessment of particles, or chemical or physical property of milk is activated or controlled by the controlling means controlling the milking.

25 48. A method according to any of the preceding claims, wherein at least one of the assessment of particles, or chemical or physical property of milk is activated or



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controlled substantially automatically, i.e. substantially without manual intervention.

49. A system for regulating a milking process, said system comprising

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- i) detecting means for identifying at least one volume of milk,
  - ii) means for assessing particles in the identified volume by either
    - a) counting of substantially individual somatic cells in the volume of milk, or
    - b) assessing at least one property of at least one biological particle in the volume of milk
  - iii) storage means for storing and providing at least one result of the assessment of particles in the identified volume of milk,
  - 15 iv) storage means for storing and providing at least one predetermined milk quality parameter,
  - v) processing means for correlating the at least one result provided in iii) to the at least one predetermined milk quality parameter provided in iv), and
  - 20 vi) means for regulating the milking process based on the correlation obtained in step v).

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50. A system according to claim 49, said system further comprising means for assessing at least one chemical or physical property of the milk, said assessment being preferably made substantially simultaneously with the assessment of the particles in the identified volume of milk.

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51. A system according to claim 49 or 50, wherein the result of the counting of individual somatic cells is correlated to a value substantially representing the

number of somatic cells per volume of milk, by the use of one or more calculated and/or predetermined parameter(s).

52. A system according to any of claims 49 to 51, wherein the estimated and/or  
5 calculated relative error of precision in the counting of the number of individual  
somatic cells is at the most 30%, preferably at the most 20%, more preferably at  
the most 15%, more preferably at the most 10%, more preferably at the most  
5%, more preferably at the most 2%.

53. A system according to any of claims 49 to 52, wherein the estimated and/or calculated relative error of accuracy in the counting of the number of individual somatic cells is at the most 30%, preferably at the most 20%, more preferably at the most 15%, more preferably at the most 10%, more preferably at the most 5%, more preferably at the most 2%.

54. A system according to claim 49, wherein the assessment of particles is the counting of biological particles present in the milk, the biological particles having diameter of more than 0.1 mm, preferably the biological particles having diameter of more than 0.5 mm, more preferably the biological particles having diameter of more than 1 mm, more preferably the biological particles having diameter of more than 2 mm, more preferably the biological particles having diameter of more than 5 mm.

55. A system according to claim 49 or 54, wherein the biological particles are one or  
several of: particles containing protein, particles containing somatic cells,  
particles containing body tissue.

56. A system according to claim 49, wherein the assessment of particles is the counting of blood particles.

57. A system according to claim 49, wherein the assessment of one or more chemical properties is the estimation of the concentration and/or the level of one or more of: fat, protein, lactose, citric acid, urea, haemoglobin, ketones, carbon dioxide, oxygen, pH, potassium, calcium, sodium.

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58. A system according to claim 49, wherein the assessment of one or more physical properties is the measurement of one or more of: temperature, conductivity, light scatter.
59. A system according to any of claims 49 to 54, wherein the assessment of individual somatic cells and/or the correlation of the counting to a value substantially representing the number of somatic cells per volume of milk is done for one or more individual quarter(s).
60. A system according to any of claims 49 to 59, wherein the regulation of the handling of the milk is done individually for milk from one or more quarter(s).
61. A system according to any of claims 49 to 60, further comprising detection means for identifying the animal and one or more information concerning the time of previous milking and/or one or more information concerning the health of the animal.
62. A system according to any of claims 49 to 61, wherein the regulation of the handling of the milk is directing the milk to one or more storage means and/or outlets.
63. A system according to any of claims 49 to 62, wherein at least one of the result of the assessment of the volume of milk is/are transferred to a storage means, wherein the result of identification of the animal is stored, the data of the storage means being available to computing means.
64. A system according to any of claims 49 to 63, wherein the milking apparatus is a automatic milking system.
65. A system according to any of claims 49 to 74, wherein the assessment of particles is performed by means of automated microscopy methods.

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66. A system according to any of claims 49 to 65, wherein the assessment of particles is performed by automated microscopy performed by creating a spatial image representation of electromagnetic irradiation from an exposing domain containing a sample of the milk and performing a quantitated detection of the image.

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67. A system according to any of claims 49 to 66, wherein the volume identified is in the range between 0.01  $\mu$ l and 20  $\mu$ l.

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68. A system according to claim 67, wherein the volume is in the range between 0.04  $\mu$ l and 4  $\mu$ l.

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69. A system according to any of claims 49 to 68, wherein the assessment of any chemical property is based on spectrophotometric measurement, the spectrophotometric measurement being, e.g., one or several of; mid-infrared attenuation, near-infrared attenuation, visible attenuation, ultra-violet attenuation, photoluminescence, raman scatter, nuclear magnetic resonance.

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70. A system according to any of claims 49 to 69, wherein the assessment of any chemical property is based on potentiometric measurement, preferably by the use of an ion selective electrode.

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71. A system according to any of claims 49 to 70, wherein the volume of milk being assessed is acquired and/or identified substantially during the entire milking, preferably where the composition of the milk is a substantial representation of the entire milk being milked.

72. A system according to any of claims 49 to 71, wherein the volume of milk being assessed is collected at different times during milking, preferably where the result of one or more assessment can be correlated to the property of the entire milk being milked.

73. A system according to any of claims 49 to 72, comprising a substantially disposable device comprising a sample compartment.

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74. A system according to claim 73, wherein at least one of the assessment of particles, or chemical or physical property of milk is performed in a substantially disposable device.

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75. A system according to claim 74, wherein the device is discarded or disposed of in the event it has become substantially empty of any chemical or reagent used for the assessment.

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76. A system according to any of claims 49 to 75, wherein at least one of the assessment of particles, or chemical or physical property of milk is performed in a domain where at least one physical dimension of the domain substantially partly determines the volume of the domain, and where the at least one physical dimension is substantially different during at least a part of any period when a sample is introduced to the domain and at least a part of any period when a measurement or detection is performed, preferably where the effect is such that the volume of the domain is substantially larger during at least a part of any period when a sample is introduced to the domain than in at least a part of any period when a measurement or detection is performed.

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77. A system according to claim 76, wherein the volume during at least a part of any period when a sample is introduced to the domain is at least 10% larger than the volume during at least a part of any period when a measurement or detection is performed, preferably where the volume is 25% larger, more preferably where the volume is 50% larger, more preferably where the volume is 100% larger, more preferably where the volume is 200% larger, more preferably where the volume is 400% larger.

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78. A system according to any of claims 49 to 77, wherein at least one of the assessment of particles, or chemical or physical property of milk is activated or controlled by the controlling means controlling the milking.

79. A system according to any of claims 49 to 78, wherein at least one of the assessment of particles, or chemical or physical property of milk is activated or

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controlled substantially automatically, i.e. substantially without manual intervention.

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